

Claims

1. A method for the protection of a poikilothermic fish against infection by the bacterial pathogen *Piscirickettsia salmonis* comprised of administering either intraperitoneally, by immersion, or orally or by any combination of routes to said animal an immunogenic amount of a pharmaceutical composition comprising a principal antigen, the OspA lipoprotein, its variants, its non-lipidated form, or antigenic peptides derived or synthesized thereof, with or without an adjuvant.
2. A method as in claim 1 where the OspA antigen or a variants thereof are fused to at least one other protein or protein fragment either at the N or C terminus or both where that protein may be either used to facilitate expression and/or the formation of insoluble intracellular aggregates (inclusion bodies), soluble intracellular, extracellular, or periplasmic protein.
3. A method as in claim 1 where the OspA antigen or a variants thereof are fused to other proteins or protein fragments where those proteins or protein fragments are lymphocyte T and/or B cell epitopes.
4. A method as in claim 3 whereby all vaccine antigens against any bacterial, viral and/or parasitic diseases of fin fish has been fused to other proteins or protein fragments where those proteins or protein fragments are any lymphocyte T and/or B cell epitopes.
5. A method as in claim 3, where the said vaccine or variants thereof are encapsulated in or adsorbed to or are in the form of an insoluble polymeric matrix.
6. A method as in claim 5, where the principle OspA antigen, its variants, fragments, fusion proteins, or synthetic peptides thereof comprise sequence homologues of the OspA protein.
7. A method as in claim 6 where the vaccine antigen is formulated with or without an adjuvant.
8. A method as in claim 7 whereby any recombinant vaccine antigen, its variants or fusion protein constructs thereof are used as a vaccine, with or without other related or non-related vaccine immunogens or adjuvants singly or in combination, against any fin-fish disease caused by either a virus, bacteria or parasite.
9. A method as in claim 6 where the route of administration is of either a protein, lipoprotein or DNA vaccine version singly or in combination is administered either orally, intraperitoneally, intramuscularly, intradermally or by immersion or spraying or by any combination of these methods.

10. A method as in claim 6, where DNA of a sequence corresponding to that of *ospA*, fragments or synthetic oligonucleotides thereof or of DNA sequence homologues of *ospA*, fragments or synthetic oligonucleotides derived thereof are used as a vaccine.

11. A method as in claim 3, where the principle antigen is either that corresponding to OspA or a OspA homologue where the sequence has been optimized for expression in a suitable expression host microorganism such as an *E. coli* bacterial strain.

12. A method as in claim 3 where the expression of the OspA protein, its variants, lipoprotein version or antigenic peptides derived or synthesized thereof in *E. coli* is effected by a promoter.

13. An immunological method for the detection of humoral antibody to protein OspA or to *P. salmonis* in sera of poikilothermic fishes where either the OspA protein, a fragment or synthesized peptide thereof or OspA and its fusion partner are used to adsorb or bind to fish immunoglobulin from fish sera.

14. A method whereby any prokaryotic or eukaryotic expression systems are used to express the OspA protein, its variants, a fragment or synthesized peptide thereof, a fusion partner-OspA protein thereof or where OspA proteins or protein fragments are expressed with T and/or B cell epitopes.

15. An isolated nucleic acid fragment encoding a 17 kDa protein, wherein said protein is immunoreactive with anti- *P. salmonis* serum, and wherein said protein has an amino acid sequence of SEQ ID NO: 2 encompassing amino acid substitutions, additions and deletions that do not alter the function of said protein.

16. The nucleic acid fragment of claim 15, comprising a contiguous sequence of SEQ ID NOs:3 & 5 or the full length complement thereof.

17. The nucleic acid fragment of claim 15 operatively linked to a promoter.

18. The nucleic acid fragment of claim 17 wherein the promoter is a recombinant promoter.

19. A vaccine comprising a contiguous nucleic acid sequence of SEQ ID NOs: 1, 3 & 5.

20. A vector comprising a contiguous nucleic acid sequence of SEQ ID NOs: 1, 3 & 5.
21. The vector of claim 20, wherein the vector is an expression vector capable of expressing a peptide encoded by SEQ ID NOs: 1, 3 & 5..
22. A host cell comprising the nucleic acid fragment of SEQ ID NOs: 1, 3 & 5.
23. A method for producing a recombinant 17 kDa antigen of *P. salmonis* comprising the steps as outlined in Examples 4 & 5.
24. A method for determining previous sensitization of a subject with the OspA polypeptide of *P. salmonis* comprising the steps as outlined in Example 6.
25. Use of the OspA polypeptide or DNA encoding the gene for OspA as well as those DNA regions flanking that gene of *P. salmonis* in the manufacture of a diagnostic agent.
26. The method of incorporation of highly immunogenic promiscuous TCE's into one or more chimeric fusion proteins in fish.
27. The method as defined in claim 26, wherein the fish is a selected salmonid.
28. The method of incorporation of highly immunogenic promiscuous TCE's into OspA fusion protein to elicit immunostimulatory effects in the immune system of fish.
29. The method as defined in claim 28, wherein the fish is a selected salmonid.
30. The method as defined in claims 28, implemented by a vaccine.
31. A vaccine for eliciting immunostimulatory effects in the immune system of fish comprising selected highly immunogenic promiscuous TCE's incorporated into one or more chimeric fusion proteins.
32. A vaccine as defined in claim 31, wherein the chimeric fusion protein is OspA.

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